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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,179	09/24/2003	Bernhard O. Palsson	242993US55CONT	4045
22850	7590	06/29/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			FALK, ANNE MARIE	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,179

Applicant(s)

PALSSON ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-98 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 36-98 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The preliminary amendment filed September 24, 2003 has been entered. Claims 1-35 were cancelled and Claims 36-98 were newly added.

Accordingly, Claims 36-98 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 36-63, drawn to a method for generating a tissue, classified in class 435, subclass 372.
- II. Claims 64-98, drawn to a method for providing a therapeutic benefit to a patient in need thereof, classified in class 424, subclass 93.7.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions I and II are patentably distinct because the inventions are drawn to mutually exclusive and independent methods. The inventions as claimed are not obvious variants because therapeutic protocols are not obvious over non-therapeutic protocols. Furthermore, methods of transferring cells in a manner that results in the generation of a tissue is not obvious over methods of transplantation that do not result in the generation of a tissue. Each of these methods require physically and functionally distinct elements. The methods require the use of different starting materials, have different modes of operation, and produce distinct outcomes. The method of the invention of Group I requires the generation of a

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tissue, which the method of the invention of Group II does not. Furthermore, the method of the invention of Group II requires a treatment protocol and treatment effect, which is not required for the method of the invention of Group I. Thus, the method of the invention of Group I is patentably distinct from the method of the invention of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper. The search and examination of each invention group would constitute an serious burden on the Office, as each group requires a separate search and consideration of issues separately applicable to each group.

Each of the inventions of Groups I and II requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the method of the invention of Group I requires consideration of issues relating to enablement for generating a tissue *in vivo* upon transplantation of stem or progenitor cells, whereas the method of the invention of Group II requires consideration of issues relating to enablement for producing a treatment effect in a patient upon transplantation of cultured bone marrow cells. The method of the invention of Group II does not require *in vivo* generation of a tissue. Thus, the searches required for the inventions of Groups I and II are not coextensive. For example, a search for the method of the invention of Group I, which requires generation of a tissue, would not necessarily identify art teaching the method of the invention of Group II, which requires a treatment protocol and treatment effect. Additional searching would be required to cover the invention of Group II. Likewise, a search for the method of the invention of Group II would not necessarily identify art teaching the method of the invention of Group I. Additional searching would be

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required to cover the invention of Group I. Thus, search and examination of both claimed inventions in a single patent application constitutes a serious burden on the Office.

With regard to burden, MPEP § 808.02 states that, to establish that there would be a serious burden on the examiner if restriction is not required,

“the examiner must show by appropriate explanation one of the following:

(A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.” (emphasis original)

Thus, to establish that a serious burden exists, it is sufficient to show separate classification of the inventions. The instant inventions have separate classifications and require separate search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Election of Species

Upon election of either group, Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following cell types, as set forth in the claims:

- A. Human peripheral blood mononuclear cells.
- B. Human bone marrow cells.
- C. Human fetal liver cells.
- D. Human cord blood cells.
- E. Human spleen cells.

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The different cell types as outlined in the species election requirement A-E represent distinct inventions because they are drawn to different cell types that are structurally and functionally distinct, having very different biological properties. The different cell types require separate searches. The cell types are not so related as to be considered obvious variants. Furthermore, there is nothing on the record to suggest that the cell types are obvious variants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species associated with the elected invention, even though this requirement is traversed.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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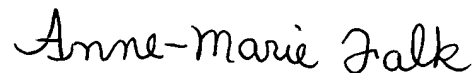
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday from 10:00 AM to 8:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.



ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER